

## **REMARKS**

Applicants have received and carefully reviewed the Office Action mailed March 4, 2004. Claims 1-69 remain pending, with all claims standing rejected. Reconsideration and reexamination are respectfully requested.

In paragraph 2 of the Office Action, claims 1-3, 7-8, 12-13, 17-19, 23-24, and 28-29 were rejected as being anticipated by U.S. Patent No. 5,391,191 to Holmström. All of these claims have one of claims 1 or 17 as a base claim. Currently pending claims 1 and 17 have been amended to incorporate previous claims 4 and 20. Applicants note that neither claim 4 nor claim 20 were included in this rejection, and as further explained below, previously pending claims 4 and 20 are believed to be allowable over Holmström. By the amendment, the rejections are rendered moot, and further, the remarks below illustrate that the rejections of claims 12-13 and 28-29, which depend from claims 1 and 17, are overcome as well, at least because claims 1 and 17 are in condition for allowance over the Holmström reference.

With respect to claims 7-8 and 23-24, the recited phrase "approximately 1 millisecond" in claims 7 and 23 has been replaced with "1 millisecond". As more fully quoted below, Holmström, in column 9, lines 39-45, states that a stimulus pulse of longer duration than 1 millisecond is unusable because it would prevent accurate detection of muscle response. Therefore, it is believed that Holmström does not actually disclose a pulse width greater than one millisecond. The removal of the word "approximately" is included to prevent overlap with Holmström in these claims. With respect to claims 2-3 and 18-19, these claims have been amended to now depend from claims 7 and 23, respectively. In light of this amendment and these remarks, it is believed that each of claims 2-3, 7-8, 18-19, and 23-24 are now in condition for allowance.

In paragraph 3 of the Office Action, claims 1, 17, 33, 49 and 65-69 were rejected under 35 U.S.C. §102(e) as being anticipated by KenKnight, U.S. Patent No. 6,148,230. Each of claims 1, 17, 33 and 49 have been amended to incorporate elements from claims 4, 20, 36, and 52, respectively, now reciting applied voltage levels. It does not appear that KenKnight provides particular ranges for voltage levels, instead making only brief, general references to energy levels in terms of Joules. Therefore, a recited element of each of claims 1, 17, 33 and 49 is not

included in the disclosure of KenKnight, such that claims 1, 17, 33 and 49, along with dependent claims 65-69, are believed allowable over KenKnight.

In paragraph 5 of the Office Action, claims 4-6, 9-11, 14, 20-22, 25-27 and 30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Holmström. After careful review of the cited reference, Applicants respectfully disagree.

With respect to claims 4-6 and 20-22, the Examiner stated:

Holmstrom discloses the claimed invention except for the monophasic waveform having a peak voltage of approximately 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform peak voltage as taught by Holmstrom with the monophasic waveform peak voltages of 25 Volts to approximately 50 Volts, approximately 50 Volts to approximately 75 Volts, and approximately 75 Volts to approximately 100 Volts, since applicant has not disclosed that these particular monophasic waveform peak voltages provide any criticality and/or unexpected results and it appears that the invention would perform equally well with any monophasic waveform peak voltage such as 2.5 Volts, or 5.0 Volts taught by Holmstrom for pacing the heart.

Office Action at Page 4.

However, on thorough review of the Holmström patent, Applicants can find no indication that Holmström discusses or fairly suggests voltages even approaching ranges exceeding 25 volts. Indeed, Holmström discusses at various places the fact that reduced voltages are preferred because these lower voltages reduce power consumption. The low voltages function in part for Holmström because these pulses are applied directly to the heart muscle, as noted at column 4, lines 23-29. As is well known in the art, power consumption is directly proportional to the square of voltage ( $P = V^2/Z$ ). Claims 4 and 20, as well as claims 5, 6, 21 and 22, recite voltage levels that are multiples of those suggested by Holmström. For example, the lowest recited voltage is 25 volts, which, if incorporated by Holmström, would result in a twenty-five-fold increase in power consumption over the maximum 5 volts suggested by Holmström.

Furthermore, the devices discussed in this field are generally implantable medical devices, such that there are size limitations that make these ranges non-obvious in this field. For example, to achieve a 25 volt pulse with the structure suggested by Holmström in Figure 1, it appears that one would need to add a plurality of additional switches as well as either capacitors

or batteries. If the structure of Holmström in Figure 1 is used, a much larger battery could be used, or several batteries, or several capacitors (for charging in parallel and discharging in series), with each of larger batteries, more batteries, or multiple capacitors taking up additional space.

The range disclosed by Holmström is limited to voltages below 5 volts. Therefore, it is believed that the voltage levels recited in claims 4-6 are well outside of a reasonable range that one would understand from Holmström as being appropriate. Therefore, Applicants believe that the Examiner did not establish a *prima facie* case of obviousness with respect to previously pending claims 4-6, as the recited ranges do not overlap that identified in Holmström and are well away (multiples of five or more) from the illustrated ranges.

Furthermore, Holmström teaches reducing the energy consumption and provides the doubling to 5 volts as an example where “the voltage doubling is activated only when, in the case of the simulation with the available battery voltage  $U_0$ , the pulse duration  $t_1$ ,  $t_6$  exceeds a predetermined maximum value (in this case, 1 ms). Holmström at column 9, lines 58-61. It appears, therefore, that Holmström teaches away from going above and outside of the range illustrated. As such, Applicants believe that, even if a *prima facie* case of obviousness has been presented, the teaching away by Holmström has overcome the Examiner’s remarks. See MPEP 2144.05(III). (“A *prima facie* case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention”).

In light of the above remarks, it is believed that previously pending claims 4-6 and 20-22 were patentable over the cited reference. In the above amendments, claims 1 and 17 were amended to incorporate claims 4 and 20, respectively. Therefore, each of claims 1 and 17 are believed to be in condition for allowance over Holmström. Claims 5, 6, 21 and 22 have been amended to incorporate the recitations of their previous base claims, claims 1 and 17, respectively. Again, each of claims 5, 6, 21 and 22 are believed to be patentable over the cited reference. Claim 14 derives dependency from claim 1, and claim 30 derives dependency from claim 17, such that both claims 14 and 30 are also believed to be in condition for allowance.

Claims 4 and 20 have been amended to depend from claims 7 and 23, respectively, such that each of these claims is also believed to be in condition for allowance in light of the above remarks and amendments.

Under paragraph 5, the Examiner also states:

With respect to claims 9-11, and 25-27, Holmstrom discloses the claimed invention except for the monophasic waveform having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform pulse width as taught by Holmstrom with monophasic waveforms having a pulse width between approximately 10 milliseconds and approximately 20 milliseconds, approximately 20 milliseconds and approximately 30 milliseconds, and approximately 30 milliseconds and approximately 40 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and/or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as approximately 1 millisecond as taught by Holmstrom for applying pacing pulses.

Office Action at Pages 4-5. However, after careful review of Holmström, Applicants believe that Holmström teaches away from the recited ranges. More particularly, Holmström states:

If the stimulation sensitivity of the tissue decreases, as is illustrated by the voltage curve  $U'$  and the associated charge curve  $Q'$ , then an increase in the stimulation energy is required for the successful stimulation. To this end, with constant stimulation voltage  $U_0$ , the pulse duration  $t_1$ ,  $t_6$ , of the stimulation pulses is increased until such time as a value of approximately 1 ms is reached. Beyond this value, the total duration in the case of the bipolar stimulation pulse (37) would become too long for a detection of the reaction of the tissue to the stimulation, for which reason in order to achieve a further increase in the stimulation energy a doubled battery voltage  $2U_0$  is set by means of the voltage doubler circuit (7, cf. FIG. 1), whereby a reduction of the pulse duration  $t_1$  to  $t_2'$  arises.

Holmström at column 9, lines 35-49. In short, Holmström clearly states that a pulse duration of longer than approximately 1 ms is too long and will interfere with detection functions. The disclosed durations in Holmström do not span the durations recited in claims 9-11 and 25-27 (each of which exceeds 10 milliseconds), such that a *prima facie* non-patentability position has not been established, as selection of a narrow range within a broad disclosed range would require actual disclosure of the broad range. Further, Applicants again note that teaching away by Holmström makes the ranges recited in claims 9-11 and 25-27 non-obvious, as noted in MPEP 2144.05(III), quoted above. It should be noted that the above amendments slightly change the

dependency, but not the recited elements, of claims 9-11 and 25-27, which now use claims 7 and 23, respectively, as base claims now. In light of these remarks, claims 9-11 and 25-27 are all believed to be patentable over the cited reference.

In paragraph 6 of the Office Action, claims 15-16 and 31-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Holmström in view of Florio et al., U.S. Patent No. 6,519,493. Florio et al. is cited in the rejection as teaching pacing in the range of 60-80 beats per minute. However, in light of the above remarks with respect to Holmström, as applied to claims 1 and 17, a *prima facie* case has not been established by the Examiner with respect to those claims. Further, it does not appear to Applicants that Florio et al. suggest the voltage levels recited in claims 1 and 17. Therefore, claims 15-16 and 31-32 are believed to be in condition for allowance.

In paragraph 7 of the Office Action, claims 34-35, 39-40, 44-45, 50-51, 55-56 and 60-61 were rejected under 35 U.S.C. §103(a) as being unpatentable over KenKnight in view of Holmström.

Claims 34-35 now depend from claim 39, as does claim 40. Claims 50-51 now depend from claim 55, as does claim 56. Claims 39 and 55 have been amended to be independent claims reciting pulse periods between 1 millisecond and approximately 40 milliseconds. As noted above, Holmström does not disclose pulse periods in this range, and indeed teaches away from providing pulses having durations in excess of 1 millisecond. The Examiner has not identified where in KenKnight this gap in the disclosure of Holmström is remedied, and further, it does not appear to Applicants that KenKnight can overcome the teaching away by Holmström. Therefore, each of claims 34-35, 39-40, 50-51 and 55-56 are believed to be patentable over the cited combination.

With respect to claims 44-45 and 60-61, these claims depend from claims 33 and 49, respectively. Independent claims 33 and 49 both recite pulse amplitudes in the range of 25-50 volts, substantially higher than those disclosed by Holmström and falling in a range that Holmström appears to teach away from. As noted above, KenKnight does not provide added disclosure with respect to applied voltage levels. Therefore, Applicants assert that each of claims 33 and 49, and therefore their dependent claims 44-45 and 60-61, are patentable over the cited combination.

In paragraph 8 of the Office Action, claims 36-38, 41-43, 46-48, 52-54, 57-59, and 62-64 were rejected as being unpatentable over KenKnight in view of Holmström.

With respect to claims 36-38 and 52-54, the Examiner makes similar suggestions with respect to the disclosure of Holmström as before with respect to claims 4-6 and 20-22. As noted above, it is believed that the recited ranges fall well outside of that which is disclosed or fairly suggested by Holmström. KenKnight does not appear to provide any further guidance to broaden the suggested/disclosed range. Therefore, the ranges of voltages recited in claims 36-38 and 52-54 are believed to be non-obvious in view of the cited references. Applicants note that claims 37, 38, 53 and 54 have been amended to be independent claims. Claim 36 now relies on claim 39 as a base claim and, therefore, also recites the duration as discussed above. Claim 52 now relies on claim 55 as a base claim, also reciting a duration. In light of the various remarks with regards to the voltage and time ranges recited, each of claims 36-38 and 52-54 are believed to be in condition for allowance because they recite ranges that fall outside of, and which are non-obvious in view of, the ranges cited.

With respect to claims 41-43 and 57-59, the Examiner makes similar comments to those noted above with respect to claims 9-11 and 25-27. It should be noted that claims 41-43 now have claim 39 as a base claim, and claims 57-59 now have claim 55 as a base claim. For at least reasons similar to those given above with respect to claims 9-11 and 25-27, it is believed that Holmström does not disclose or render obvious the recited ranges; indeed, Holmström appears to teach away from pulses having a duration over 1 millisecond. Further, KenKnight does not appear to provide any further guidance. Therefore, the recited durations for the pulses are far outside that which is disclosed and/or obvious in view of the cited references, and thus claims 41-43 and 57-59 are believed to be in condition for allowance.

With respect to claims 46 and 62, these claims (through some intervening claims) depend from claims 33 and 49, respectively. Independent claims 33 and 49 both recite pulse amplitudes in the range of 25-50 volts, substantially higher than those disclosed by Holmström and falling in a range that Holmström appears to teach away from. As noted above, KenKnight does not provide added disclosure with respect to applied voltage levels. For at least this reason, claims 46 and 62 are believed to be patentable over the cited combination.

In paragraph 9 of the Office Action, claims 47-48, 63 and 64 were rejected under 35 U.S.C. §103(a) as being unpatentable over KenKnight in view of Holmström and Florio et al. Florio et al. is cited in the rejection as teaching pacing in the range of 60-80 beats per minute. However, in light of the above remarks with respect to Holmström and KenKnight, as applied to claims 36 and 52, a *prima facie* case has not been established by the Examiner with respect to those claims. Independent claims 33 and 49 have been amended to incorporate the voltage levels previously recited in dependent claims 36 and 52, and thus it is believed that these claims are patentable over KenKnight in view of Holmström. It does not appear to Applicants that Florio et al. suggest the voltage levels recited in claims 33 and 49. As such, the cited combination of three references does not provide disclosure of, nor render obvious, the cited ranges in the base claims for claims 47-48 and 63-64. Therefore, claims 47-48 and 63-64 are believed to be in condition for allowance.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

Date: \_\_\_\_\_

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